CLAIMS

What is claimed;

1. A pharmaceutical gel composition comprising:
a solvent vehicle,
at least one water-insoluble swellable mucoadhesive polymer,
at least one pH-sensitive film-forming polymer, and
at least one molecule of interest.

2. The gel of claim 1, wherein the solvent vehicle is comprised of at least 25 to 100 parts water or buffered water with 0 to 75 parts of ethanol, propylene glycol, glycerin, polyethylene glycol, or combinations thereof.

3. The gel of claim 1, wherein the water-insoluble swellable mucoadhesive polymer is polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol.

4. The gel of claim 1, wherein the water-insoluble swellable mucoadhesive polymer is Noveon or Carbomer.

5. The gel of claim 1, wherein the water-insoluble swellable mucoadhesive polymer is present at a concentration of from 0.1% to 20% by weight.

6. The gel of claim 1, wherein the pH-sensitive polymer is a copolymer of methacrylic acid and acrylic or methacrylic ester.

7. The gel of claim 1, wherein the pH-sensitive polymer is present at a concentration of from 0.05% to 10% by weight.

8. The gel of claim 1, wherein the pH-sensitive polymer is a Eudragit polymer, or a chemical derivative thereof.

9. The gel of claim 1, wherein the molecule of interest comprises an active pharmaceutical such as an antimicrobial, antiviral, antiinflammatory, antiseptic, antihistamine, a local anesthetic, a disinfectant, a keratolytic, an analgesic, an anti-migraine, an anti-fungal, a sweetener, a flavoring agent, a diagnostic agent, or combination thereof.

10. The gel of claim 1, wherein the molecule of interest is amlexanox.

11. The gel of claim 1, wherein the molecule of interest is triclosan.

12. The gel of claim 1, wherein the molecule of interest is hirudin.

13. The gel of claim 1, wherein the molecule of interest is plasmid DNA.

14. The gel of claim 1, wherein the molecule of interest is lidocaine, benzocaine, or dyclonine.

15. The gel of claim 1, wherein the molecule of interest is at least one benzodiazepine drug or derivative thereof.

16. A pharmaceutical gel which when applied to the skin or mucosal surface forms a film, said gel comprising a solvent vehicle, at least one water-insoluble swellable mucoadhesive polymer, at least one pH-sensitive film-forming polymer, and at least one molecule of interest, wherein said film is formed due to changes in pH and desolvation of the polymer, and wherein said film provides for the delivery of the molecule of interest to or through the application site.

17. The gel of claim 16, wherein the solvent vehicle is comprised of at least 25 to 100 parts water with 0 to 75 parts of ethanol, propylene glycol, glycerin, polyethylene glycol, or combinations thereof.

18. The gel of claim 16, wherein the water-insoluble swellable mucoadhesive polymer is polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol.

19. The gel of claim 16, wherein the water-insoluble swellable mucoadhesive polymer is Noveon or Carbomer.

20. The gel of claim 16, wherein the water-insoluble swellable mucoadhesive polymer is present at a concentration of from 0.1% to 20% by weight.

21. The gel of claim 16, wherein the pH-sensitive polymer is a copolymer of methacrylic acid and acrylic or methacrylic ester.

22. The gel of claim 16, wherein the pH-sensitive polymer is present at a concentration of from 0.05% to 10% by weight.

23. The gel of claim 16, wherein the pH-sensitive polymer is a Eudragit polymer, or chemical derivative thereof.

24. The gel of claim 16, wherein the molecule of interest comprises an active pharmaceutical such as an antimicrobial, antiviral, antiinflammatory, antiseptic, antihistamine, a local anesthetic, a disinfectant, a keratolytic, an analgesic, an anti-migraine, an anti-fungal, a sweetener, a flavoring agent, a diagnostic agent, or combination thereof.

25. The gel of claim 16, wherein the molecule of interest is amlexanox.

26. The gel of claim 16, wherein the molecule of interest is triclosan.

27. The gel of claim 16, wherein the molecule of interest is a peptide or protein.

28. The gel of claim 16, wherein the molecule of interest is hirudin.

29. The gel of claim 16, wherein the molecule of interest is plasmid DNA.

30. The gel of claim 16, wherein the molecule of interest is lidocaine, benzocaine, or dyclonine.

31. The gel of claim 16, wherein the molecule of interest is at least one benzodiazepine drug or derivative thereof.

32. The gel of claim 16, wherein the application site is the skin, mouth, vagina, nose, nasal cavity, or other accessible mucosal site.

33. A wax-film composite comprised of a pH-sensitive mucoadhesive layer and a water-insoluble wax layer.

34. The wax-film composite of claim 33, wherein the pH-sensitive mucoadhesive layer is present at a concentration of 20% to 90% by weight, and the water-insoluble wax layer is present at a concentration of 10% to 80% by weight.

35. The wax-film composite of claim 33, wherein said pH-sensitive mucoadhesive water-insoluble layer is comprised of:

at least one water-insoluble swellable mucoadhesive polymer,

at least one pH-sensitive film-forming polymer, and

at least one molecule of interest.

36. The wax-film composite of claim 33, wherein the water-insoluble swellable mucoadhesive polymer is polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol.

37. The wax-film composite of claim 33, wherein the water-insoluble swellable mucoadhesive polymer is Noveon or Carbomer.

38. The wax-film composite of claim 33, wherein the water-insoluble swellable mucoadhesive polymer is present in the pH-sensitive mucoadhesive layer at a concentration from 0.1% to 20% by weight.

39. The wax-film composite of claim 33, wherein the pH-sensitive polymer present in the pH-sensitive mucoadhesive layer is a copolymer of methacrylic acid and acrylic or methacrylic ester.

40. The wax-film composite of claim 33, wherein the pH-sensitive polymer is present in the pH-sensitive mucoadhesive layer at a concentration of from 0.05% to 10% by weight.

41. The wax-film composite of claim 33, wherein the pH-sensitive polymer present in the pH-sensitive mucoadhesive layer is a Eudragit polymer, or chemical derivative thereof.

42. The wax-film composite of claim 33, wherein the water-insoluble wax layer comprises at least one water-insoluble pharmaceutical wax having a melting point between 40°C and 100°C and at least one water-soluble or water-swellable polymer.

43. The water-insoluble pharmaceutical wax of claim 42, wherein said wax is DENTSPLY® Utility Wax, beeswax, emulsifying wax, microcrystalline wax, carnauba wax, paraffin wax, white wax, yellow wax, or other suitable pharmaceutical wax.

44. The water-soluble or swellable polymer of claim 42, wherein said polymer is present in the insoluble wax layer at a concentration of 0.05 to 10% by weight.

45. The water-soluble or swellable polymer of claim 42 where said water-soluble or water-swellable polymer is tragacanth, polyvinyl pyrrolidone, polyvinyl alcohol, cross-linked polyacrylic acid, polyethylene glycol, a cellulose polymer derivative, or other suitable pharmaceutical polymer that is water-soluble or water-swellable.

46. The wax-film composite of claim 33, wherein the molecule of interest is contained in and released from either the pH-sensitive mucoadhesive layer or the water-insoluble wax layer.

47. The wax-film composite of claim 33, wherein the molecule of interest comprises an active pharmaceutical compound such as an antimicrobial, antiviral, antiinflammatory, antiseptic, antihistamine, a local anesthetic, a disinfectant, a keratolytic, an analgesic, an anti-migraine, an anti-fungal, a sweetener, a flavoring agent, a diagnostic agent, or a combination thereof.

48. The wax-film composite of claim 33, wherein the molecule of interest is amlexanox.

49. The wax-film composite of claim 33, wherein the molecule of interest is triclosan.

50. The wax-film composite of claim 33, wherein the molecule of interest is lidocaine, benzocaine, or dyclonine.

51. The wax-film composite of claim 33, wherein the molecule of interest is a peptide or protein.

52. The wax-film composite of claim 33, wherein the molecule of interest is at least one benzodiazepine drug or derivative thereof.

53. The wax-film composite of claim 33, wherein the molecule of interest is hirudin or hirudin complexed with a substance of opposite charge.

54. The wax-film composite of claim 53, wherein said substance of opposite charge is chitosan or protamine

55. The wax-film composite of claim 33, wherein the molecule of interest is plasmid DNA or plasmid DNA complexed with a substance of opposite charge such as chitosan, protamine, or a cationic lipid.

56. The wax-film composite of claim 33, wherein the application site is the skin, mouth, vagina, nasal cavity, or other accessible mucosal site.

57. The wax-film composite of claim 33, wherein the wax-film composite adheres to the application site for at least 1 hour.

58. The wax-film composite of claim 33, wherein the wax-film composite has a total thickness of less than 5 mm.

59. A method of making the pharmaceutical gel composition according to claim 1, comprising:

(i) adding a mucoadhesive polymer to a stirring water to form a solution that is clear and viscous,

(ii) adding the pH-sensitive film-forming polymer to the solution formed in step (i) and measuring the pH of the solution,

(iii) adding the molecule of interest to the solution of step (ii), and

(iv) forming the final gel composition.

60. A method of making the wax film composite according to claim 33, comprising:

(i) forming a homogeneous mucoadhesive film by fusing a mucoadhesive polymer and a pH-sensitive film-forming polymer,

(ii) homogeneously coating one side of the mucoadhesive film of step (i) with a melted wax composition, and

(iii) drying the wax composition to form the wax-film composite, wherein the molecule of interest is added in either step (i) or (ii), or the molecule of interest is added to the mucoadhesive side after the wax-film composite is formed.

61. A method of treating a disease or illness comprising administering to an individual in need thereof, a treatment-effective amount of the gel composition according to claim 1 comprising a molecule of interest.

62. A method of treating a disease or illness comprising administering to an individual in need thereof, a treatment-effective amount of the wax-film composite according to claim 33 comprising a molecule of interest..